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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/829,073	04/09/2001	Ke-Wen Dong	#651	7413

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EXAMINER
COOK, LISA V

ART UNIT	PAPER NUMBER
1641	

DATE MAILED: 04/20/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/829,073	DONG ET AL.	
	Examiner	Art Unit	
	Lisa V. Cook	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 December 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-21* is/are pending in the application.

4a) Of the above claim(s) *10-18,20 and 21* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-9 and 19* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-21* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *18 December 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *12/18/2004*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Request for Continued Examination

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 12/18/03 has been entered.

Request for Corrected Filing Receipt

2. Applicants request is acknowledged and the application data sheet will be corrected.

Amendment Entry

3. Applicant's response to the Final Office Action mailed 20 May 2003 (Paper filed 10/20/03) is acknowledged. The amendment filed therein has been entered. Claims 1 and 19 along with the disclosure have been. Currently, Claims 1-9, and 19 are under consideration.

OBJECTIONS WITHDRAWN

Drawings

4. The drawings in this application are objected to by the Draftsperson under 37 CFR 1.84 or 1.152 (see PTO-948).

The replacement drawings were received on 10/20/03. The Examiner finds the drawings acceptable.

NEW GROUNDS OF REJECTION NECESSITATED BY AMENDMENT

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

I. Claims 1 and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Whitmarsh et al. (Molecular human Reproduction, Vol.2, No.12, pages 911-919) in view of Chamberlin and Dean (Proceedings of the National Academy of Science, USA, Vol.87, pages 6014-6018, August 1990).

Whitmarsh et al. disclose a method for measuring the biological activity of recombinant human ZP3 (rhZP3). In the method rhZP3 is immobilized on beads and exposed to spermatozoa.

The binding between the rhZP3 and sperm is accessed sperm function/activity and the acrosomal status. See abstract, page 914, and page 915. Although Whitmarsh et al. do not specifically teach that the rhZP3 is glycosylated it does give the means by which the rhZP3 can be glycosylated [incorporation of canine pancreatic microsomal membranes] and detected [Amersham Ltd]. See Page 916 1st column, 2nd paragraph. Whitmarsh et al. also teach the increased binding seen in glycosylated constructs versus the non-glycosylated molecules. Applicants state, "In the present study the rhuZP3 was probably not glycosylated, yet retained some biological activity. This is perhaps surprising if we confine our thoughts to the mouse where conventional wisdom emphasizes the importance of carbohydrates in the binding of spermatozoa to the zona." See page 917 1st column – 2nd paragraph. Accordingly gylcosylated forms and non-glycosylated forms of rhZP3 were known and taught in the prior art.

Whitmarsh et al. differ from the instant invention in not specifically employing a recombinant human zona pellucida protein ZP3 expressed from human ovarian cells.

However, Chamberlin and Dean disclose this limitation. On page 6015 Human ZP3 cDNA was produced. Poly(A)+ RNA was purified from total RNA isolated from a human ovary. Also see abstract.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to employ a human ZP3 expressed from human ovaries as taught by Chamberlin and Dean in the method of Whitmarsh et al. to measuring ZP3 and sperm binding as an indicator of sperm activity because Chamberlin and Dean taught that the binding affinity between the spermatozoon and zona (ZP3) is species-specific and dependent on homologous species. See page 6014 1st column 2nd paragraph.

In other words the true binding between sperm and the zona (ZP3) is assessed when the two components are from the same species. One of ordinary skill would have been motivated to use a human ZP3 expressed from human ovary cells to bind human sperm in order to acquire accurate data with respect to human binding events.

II. Claims 2-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Whitmarsh et al. (Molecular human Reproduction, Vol.2, No.12, pages 911-919) in view of Chamberlin and Dean (Proceedings of the National Academy of Science, USA, Vol.87, pages 6014-6018, August 1990).

Please see previous discussions of Whitmarsh et al. (Molecular human Reproduction, Vol.2, No.12, pages 911-919) in view of Chamberlin and Dean (Proceedings of the National Academy of Science, USA, Vol.87, pages 6014-6018, August 1990) as set forth above.

Whitmarsh et al. in view of Chamberlin and Dean differ from the instant invention in not specifically identifying the concentration of human zona pellucida protein ZP3.

However, Whitmarsh et al. in view of Chamberlin and Dean discloses the claimed invention except for specific concentrations of ZP3. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the concentration of reagents to the specific concentrations in claims 2-8 in a binding assay as a means of optimizing the assay, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233.

III. Claim 19 is rejected under 35 U.S.C. 103(a) as being unpatentable over Whitmarsh et al. (Molecular human Reproduction, Vol.2, No.12, pages 911-919) in view of Chamberlin and Dean (Proceedings of the National Academy of Science, USA, Vol.87, pages 6014-6018, August 1990) and in further view of Foster et al. (U.S.Patent#4,444,879).

The teachings of Whitmarsh et al. (Molecular human Reproduction, Vol.2, No.12, pages 911-919) in view of Chamberlin and Dean (Proceedings of the National Academy of Science, USA, Vol.87, pages 6014-6018, August 1990) are set forth above.

The cited references fail to teach the assay as a kit. However, kits are well known embodiments for assay reagents. Foster et al. (U.S. Patent #4,444,879) describe one example. In their patent kits including the reactant reagents, a micro plate, positive controls, negative controls, standards, and instructions are taught. See figure 6, and column 15, lines 10-34.

It would have been prima facie obvious to one of ordinary skill in the art at the time of applicant's invention to take the binding/detection assay as taught by Whitmarsh et al. (Molecular human Reproduction, Vol.2, No.12, pages 911-919) in view of Chamberlin and Dean (Proceedings of the National Academy of Science, USA, Vol.87, pages 6014-6018, August 1990) and format them into a kit because Foster et al. teach that it is convenient to do so and one can enhance sensitivity of a method by providing reagents as a kit. Further, the reagents in a kit are available in pre-measured amounts, which eliminates the variability that can occur when performing the assay.

Response to Arguments

Applicant contends that all prior art references did not teach glycosylated recombinant ZP3 expressed from human ovaries. This argument was carefully considered and found persuasive. The references of Whitmarsh et al. (Molecular human Reproduction, Vol.2, No.12, pages 911-919) in view of Chamberlin and Dean (Proceedings of the National Academy of Science, USA, Vol.87, pages 6014-6018, August 1990) have been added to teach this limitation.

6. For reasons aforementioned, no claims are allowed.

Remarks

7. Prior art made of record and not relied upon is considered pertinent to the applicant's disclosure:

A. Harris (U.S.Patent#5,837,497) teaches methods related to the purification and isolation of DNA sequences encoding the zona pellucida proteins from various mammalian species. The zona pellucida is a complex matrix surrounding the mammalian oocyte, formed of glycoproteins secreted by ovarian cells. Zone pellucida (ZP) glycoproteins perform a number of different functions. For example, the mouse ZP has been shown to provide structural integrity to the matrix, to be a sperm receptor in the matrix, to induce the sperm acrosome reaction on the surface of ZP, and to maintain binding between the sperm/egg as a secondary receptor. (Column 1, Lines 24-52)

In example 11, Harris et al. isolate and purify a human DNA sequences encoding human zona pellucida proteins ZPA and ZPB. These glycoprotein structures were found to be 92.6% homologous to the instant inventive products. (MPSRCH comparing protein-protein database search utilizing Smith-Waterman algorithm - A).

B. Ozgur et al. (Molecular Human Reproduction, Vol.4, No.4, pp.318-324, 1998) teach direct evidence of the binding process dependency upon the recognition of oligosacchardes sequences associated with zona pellucida glycoproteins.

C. Harris et al. (WO 94/11019) teach methods related to the purification and isolation of DNA sequences encoding the zona pellucida proteins from various mammalian species. The zona pellucida is a complex matrix surrounding the mammalian oocyte, formed of glycoproteins secreted by ovarian cells. Zone pellucida (ZP) glycoproteins perform a number of different functions. For example, the mouse ZP has been shown to provide structural integrity to the matrix, to be a sperm receptor in the matrix, to induce the sperm acrosome reaction on the surface of ZP, and to maintain binding between the sperm/egg as a secondary receptor. (Page 1 and Page 2) In example 11, Harris et al. isolate and purify a human DNA sequences encoding human zona pellucida proteins ZPA and ZPB. These glycoprotein structures were found to be 92.6% homologous to the instant inventive products. (MPSRCH comparing protein-protein database search utilizing Smith-Waterman algorithm - A).

8. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform to the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The Group 1641 Fax number is (703) 872-9306, which is able to receive transmissions 24 hours/day, 7 days/week.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lisa V. Cook whose telephone number is (571) 272-0816. The examiner can normally be reached on Monday-Friday from 8:00 AM - 4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le, can be reached on (571) 272-0823.

Any inquiry of a general nature or relating to the status of this application should be directed to Group TC 1600 whose telephone number is (571) 272-1600.

Lisa V. Cook
Patent Examiner
Art Unit 1641
Remsen 3C-59
4/15/04

LONG V. LE
SUPERVISORY PATENT EXAMINER
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04/19/04